



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

41627b

4298 Elysian Fields Avenue
New Orleans, LA 70122

December 11, 1996

WARNING LETTER NO. 97-NOL-19

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Louis B. Viviano
President
University Plasma, Inc.
600 General Mouton
Lafayette, Louisiana 70501

Dear Mr. Viviano:

During an inspection of University Plasma, Inc., dba University Plasma Services, located at 600 General Mouton, Lafayette, Louisiana, on November 6-8, 1996, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act and Title 21 Code of Federal Regulations (21 CFR), Parts 600-680.

The violations noted involve your firm's failure to maintain for the Physician Substitute: 1) a current license and/or certification in the state of Louisiana (or any other state); 2) documentation of participation in a physician substitute program or any similar training; 3) a physician's evaluation of performance; and 4) a curriculum vitae.


The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility, as Responsible Head, to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Page - 2 - University Plasma, Inc./Lafayette, LA

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Hardin.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", written over the printed name.

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

/tjt